

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE:)
)
'318 PATENT INFRINGEMENT LITIGATION) C.A. No. 05-356 (KAJ)
) (consolidated)
)

**BARR LABORATORIES, INC. AND BARR
PHARMACEUTICALS, INC.'S MOTION TO REASSIGN CASE TO PRESERVE
THE UPCOMING TRIAL DATE OF THIS ACTION**

Defendants, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively "Barr"), hereby move to have this action reassigned to another member of this Court based on the recent confirmation of The Honorable Kent A. Jordan to the United States Court of Appeals for the Third Circuit. In support of this Motion, Barr states as follows:

I. INTRODUCTION

This Hatch-Waxman patent case, pending before Judge Jordan, involves just *two* claims of a *single* 3-page method-of-use patent, U.S. Patent No. 4,663,318 ("the '318 patent"). On January 12, 2006, Judge Jordan granted Defendants' request to expedite the resolution of this case. Specifically, Judge Jordan entered a Revised Scheduling Order requiring the parties to complete pre-trial discovery and motion practice by December 22, 2006 and try this case in a short bench trial beginning on June 4, 2007.

Defendants requested an expedited schedule in this case for one reason: the '318 patent expires on December 14, 2008.¹ Accordingly, unless this case is tried as

¹ During the May 15, 2006 Discovery Teleconference, Judge Jordan discussed the importance of complying with the expedited scheduling order. He cautioned, "that there are business imperatives that drive behavior that are far beyond my pay grade. I'm not suggesting that you're doing anything here for strategic purposes, don't get me wrong, but I am suggesting that when the folks on the defense side say, hey, we have business issues that make scheduling here important to us, I take that seriously. It's not an overriding or a factor that

scheduled (or as close thereto as possible), Barr stands little if any chance of having the case fully adjudicated (*i.e.*, through appeal) in time for Barr to receive the full benefit of the six month marketing exclusivity that is given to a successful challenger of an Orange-book listed patent.²

By this Motion, Barr simply seeks to preserve the June 2007 trial date (or a date close thereto) by having the Court reassign this case to another member of the Court given the inherent uncertainties surrounding when Judge Jordan will be replaced. Barr also is willing to consent to the jurisdiction of Magistrate Judge Thyne, who agreed to preside over this case during the last meeting with Her Honor. Plaintiffs, however, will not agree to Magistrate Thyne hearing this case.

Given Plaintiffs' resistance to Magistrate Thyne and the inherent prejudice to Barr from any delay in resolving this case, Plaintiffs have no plausible grounds for opposing this motion. To date, the parties have completed fact discovery and expert discovery. Additionally, the parties will have fully briefed claim construction by December 20, 2006 and Plaintiffs' motion for *partial* summary judgment by December 22, 2006. Apart from a hearing on the briefs (both of which are currently scheduled to be heard on January 18, 2007), there is nothing left for the parties to do other than prepare the case for a June 2007 trial date.

If Barr's motion is not granted, the effect of Judge Jordan's appointment to the Third Circuit will be a financial windfall to Plaintiffs and a huge penalty to Barr, as Barr will be deprived of the very benefit that Congress intended to provide to generic

all by itself rules the day, but I'm not unmindful of what goes on in these ANDA cases." See May 15, 2006 Discovery Teleconference Transcript p. 18 lns. 14-22 attached hereto as Exhibit 1.

² The '318 patent is listed in the FDA's Orange Book as covering Razadyne, a drug product indicated for the treatment of mild to moderate Alzheimer's disease.

pharmaceutical companies who undertake the very high risks of challenging a patent. Obviously, such a result will be highly prejudicial to Barr and ride roughshod over the Hatch-Waxman Act.

II. BACKGROUND OF CASE

A. Parties: Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively “Plaintiffs”) initially filed seven separate suits against 13 different parties alleging infringement of the ‘318 patent. All of the cases were consolidated in October, 2005. (D.I. 29). Currently, Barr and Alphapharm Pty Ltd. (“Alphapharm”) are the only remaining defendants to this litigation.⁴

B. Asserted Patent Claims: The only legal issues to be decided in this case are whether claims 1 and 4 of the ‘318 patent are rendered invalid as anticipated and/or obvious in view of selected pieces of prior art and whether the claims are enabled. For the sole purpose of expediting the case, Defendants agreed to stipulate not to contest infringement of claims 1 and 4 of the ‘318 patent (D.I. 49). Thus, the only claims that remain are Barr’s and Alphapharm’s counterclaims for declaratory judgment of invalidity of claims 1 and 4 of the ‘318 patent.

C. Trial Date. This case is scheduled for a ten (10) day bench trial from June 4, 2007 through June 15, 2007 (D.I. 81), although Barr now believes that, due to the reduction in the number of claims and the number of defendants, the case can be tried in five (5) days.

D. Patent Expiration Date. The ‘318 patent expires on December 14, 2008.

⁴ The action against defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. was dismissed without prejudice (D.I. 186) and the actions against the other four groups of defendants: (i) Actavis Group f/n/a Alpharma, Inc. and Purepac Pharmaceutical Co., (ii) Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc., (iii) Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc.; and (iv) Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd., have been stayed. (D.I. 177, 236, 258, and 298).

III. RELIEF REQUESTED


If the '318 patent is found to be invalid, Barr is statutorily entitled to exclusively market a generic version of Razadyne for a six month period prior to the expiration of the '318 patent (i.e., from June 17, 2008 through December 14, 2008). *See* 21 U.S.C. §355(j)(5)(B)(iv). Therefore, this case must be fully adjudicated, including any appeal, by June 17, 2008 for Barr to receive the benefit of this statutory right. Otherwise, Barr will be faced with a situation where it has expended a substantial amount of time and resources pursuing its claim with no hope of receiving the potential fruits of its labor. Put differently, this case will be nothing more than an academic exercise.

Currently, the trial is scheduled for June 4, 2007, leaving approximately one year for post-trial briefing and any appeal, which, even without any delays, may not be an adequate amount of time. However, if the trial is delayed, this matter certainly will not be fully adjudicated prior to the expiration of the '318 patent. Thus, based on the time sensitive nature of this case and the uncertainty as to when Judge Jordan will be replaced, Barr respectfully requests that the Court reassign this case to another member of the Court.

WHEREFORE, Barr respectfully request that the Court enter an order (i) reassigning this case to another member of the Court; and (ii) granting such further relief as the Court deems just and proper.

Respectfully submitted,

PHILLIPS GOLDMAN & SPENCE, P.A.



John C. Phillips, Jr. (Bar No. 110)
Brian E. Farnham (Bar No. 4089)
1200 N. Broom Street
Wilmington, DE 19806
(302) 655-4200

and

George C. Lombardi (admitted pro hac vice)
Taras A. Gracey (admitted pro hac vice)
Lynn M. Ulrich (admitted pro hac vice)
Mustafa A. Hersi (admitted pro hac vice)
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601
Tele: (312) 558-5600
Fax: (312) 558-5700

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